REMARKS

I.

Favorable reconsideration of this application as presently amended is respectfully requested.

Claims 1-33 are presently in the application. Claims 1-15, 21, 22, and 29 have been withdrawn from consider as being directed to non-elected inventions.

Applicants note with appreciation the examiner's allowance of claims 18 and 19.

Applicants note that claim 20 depends from claim 18. Claim 20 was not mentioned in the office action. Applicants assume that claim 20 is allowable along with its parent claim 18.

Claims 31-33 have been added. Support for claims 31-33 is found throughout the specification and in particular on page 26 lines 1-17.

II.

Applicants note the examiner's request on page 9 of the official action for a list of all pending applications that set forth similar subject matter to the present claims along with a copy of the copending claims. The applications are serial Nos. 09/121,300 (our docket No. 3295-0024 0 CONT) and 09/131,915(our docket No. 3295-0025-0 CONT). Copies of the pending claims are submitted herewith.

III.

Applicants note that on page 2 of the official action, the examiner has made the restriction requirement final.

IV.

Applicants further note that on page 2 of the official action the examiner has granted their request to add Christopher T. Kelley as an inventor.

V.

The examiner's objection to the specification on pages 2 and 3 of the official action are noted.

Applicants are submitting herewith on a separate sheet a new abstract to overcome come the examiner's objections to the abstract.

As requested by the examiner, proposed drawing corrections to Figures 1a. 1b, 2a, 2b, 3a, 3b, and 3c are submitted herewith and the specification has been amended so that the description on page 9 matches the legends on the drawings.

In addition, proposed drawing corrections to Figures 7a and 7b are submitted herewith and the specification on page 10 lines 4-7 has been amended to match the legends on the figures.

Proposed corrections to Figures 13a , 13b, 20a, 20b, 21a, 21b, 24a, and 24b are also submitted herewith. The proposed corrections to Figures 7, 13, 20, 21, and 24 change the upper case letter "A" or "B" to its corresponding lower case letter to be consistent with the reference to those figures in the specification. Page 28 line 1 of the specification points out that Figures 20a-21b illustrate examples of the various coverings described in the specification. Applicants note that the term "covering" is defined on page 37 lines 5-7.

A proposed correction to Figure 12 is submitted to illustrate the docking means 2 recited in claim 24 and described in t he specification at page 17 lines 16-21. Another proposed correction to Figure 12 is submitted to illustrate the docking means 3 recited in

claim 25 and described in the specification at page 17 line 21-page 18 line 2.

The examiner's objection to page 12 line 16 of the specification is noted. However, no text is missing. The language in line 17 should have followed after the word "invention" in line 16. The paragraph has been rewritten in order to eliminate the blank space on line 16.

As requested by the examiner, the trademark VELCRO has been capitalized throughout and accompanied by its generic terminology and the trademark POLARTEC has been capitalized on page 38 line 18 and accompanied by its generic terminology.

VI.

The examiner's objections to the drawings under 37 CFR 1.83(a) have been noted. The proposed corrections to Figure 12 illustrate the docking means 2 for suspension of the covering and the docking means 3 for attaching pads are submitted herewith for approval by the examiner. Support for the proposed corrections to Figure 12 are found throughout the specification and in particular on page 17 lines 16- 21 and page 17 line 21-page 18 line 2, respectively. A letter requesting approval of drawing changes accompanied by the proposed corrections to the drawings is submitted herewith.

VII.

Claim 30 stands rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner contends that there is no clear support for the recitation "covering fabric that can adhere to a hook portion of a hook and loop fastening system." Applicants respectfully traverse this rejection. Support for the subject matter of claim 30 is found throughout the specification and in particular on page 17 lines 16-21, in

Example 1 on page 37 (i.e., jersey knit fabric), and in Example 7 on page 39 (i.e., tubular knitted terry stockinette). The knitted fabric referred to in both of those examples inherently form loops that can adhere to a hook portion of a hook and loop fastening system as recited in claim 30.

VIII.

Claims 24, 25, and 30 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed. Support for the docking means recited in claim 24 is found on page 17 lines 16-21. Support for the docking means recited in claim 25 is found on page 17 line 21-page 18 line 2. The docking means recited in claim 24 is illustrated at 2 in proposed corrected Figure 12 and the docking means recited in claim 25 is illustrated at 3 in proposed corrected Figure 12. Clearly the docking means recited in claims 24 and 25 is not the structure illustrated in Figure 9 as incorrectly assumed by the examiner. Antecedent basis in the specification for the recitation in claim 30 is clearly found on page 17 line 16-21. In the embodiment recited in claim 30, the loop portion of the hook and loop fastening system is incorporated into the fabric during the normal knitting process in forming the knitted fabrics referred to, for example, in Examples 1 and 7 on pages 37 and 39 of the specification.

IX.

The objection to claim 26 is noted. Claim 26 has been rewritten to correct the spelling of opposite in line 2.

X.

Claims 24 and 25 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 81 and 82 of copending application serial No. 09/121,300. This rejection is respectfully traversed. Claims 81 and 82 have been canceled from application serial No. 09/121,300. Therefore, this rejection is moot.

XI.

Claims 16, 17, 23-25, 27, and 30 stand rejected under 35 USC 102(e) as being anticipated by Kania (U.S. Patent 5,830,237). This rejection is respectfully traversed.

Claim 16 and 17

Claim 16 has been amended to make clear that the remaining portion(s) comprise a "lower wear resistance" highly elastic fabric. The '237 Kania patent clearly does not teach the subject matter of claim 16 as amended. Claim 17 depends from claim 16, and therefore it patentably distinguishes over the '237 Kania patent for the reasons stated above with respect to claim 16.

Claims 23-25

The examiner has not indicated why he believes that the '237 Kania patent anticipates the subject in any of claims 23-25. Clearly the '237 Kania patent does not teach or suggest the covering comprising "fiber-on-end" fabric as recited in claim 23. The advantages of fiber-on-end fabrics are described throughout the specification and in particular on page 28 lines 9-12.. Accordingly, the subject matter in claim 23 is not anticipated by the '237 Kania patent.

The docking means recited in claims 24 and 25 is clearly not taught by the '237 Kania patent.

Accordingly, claims 23-25 are not anticipated by the '237 Kania patent.

Claim 30

The subject matter in claim 30 is not taught by the '237 Kania patent. That is, the '237 Kania patent does not teach any fastening system let alone a loop and hook fastening system as recited in claim 30.

XII.

Claims 23 stands rejected under 35 USC 102(e) as being anticipated by Kania (U.S. Patent No. 5,603,122). This rejection is respectfully traversed. There is no teaching in the '122 Kania patent of a covering comprising a "fiber-on-end" fabric as recited in claim 23. The advantages of the fiber-on-end fabric are discussed in the specification at page 28 lines 9-12.

XIII.

Claims 23 and 30 stand rejected under 35 USC 102(b) as being anticipated by Lerman (U.S. Patent No. 4,832,010). This rejection is respectfully traversed.

Claim 23

The Lerman patent does not disclose a tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for the introduction of said stump and a closed end opposite said open end. In addition, the Lerman patent does not disclose a covering comprising "fiber-on-end" fabric. The advantages of the fiber-on-end fabric are discussed in the specification at page 28 lines 9-12.

Claim 30

The Lerman patent does not disclose a tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for the introduction of said stump and a

closed end opposite said open end. In addition, the Lerman patent does not disclose a covering comprising a fabric that can adhere to a hook portion of a hook and loop fastening system. Furthermore, the Lerman patent does not disclose a covering that is coated on the inside thereof with a polymeric material. The layer 28 disclosed in Lerman is described in column 3 lines 50-55 as a thin flexible and foldable elastomeric sheet made from closed cell material. Outer layers 32 and 34 simply overlie the layer 28 and are secured by adhesive (Lerman patent at column 4 lines 58-68).

XIV.

Claim 28 stands rejected under 35 USC 103(a) as being unpatentable over Lerman (U.S. Patent No. 4,832,010) in view of Laghi (U.S. Patent No. 5,507,834). This rejection is respectfully traversed. The Lerman patent does not teach or suggest a tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for the introduction of said stump and a closed end opposite said open end. The Lerman patent also fails to teach or suggest a covering coated on the inside with a polymeric material. Further, Lerman fails to teach or suggest a covering and/or a polymeric material comprising a thermal-regulating additive. As pointed out in column 3 line 50-column 4 line 31 of the Lerman patent, the structure disclosed therein comprises a flexible foldable elasomeric base layer 28 in thin sheet form made of a closed cell material. The preferred material is neoprene rubber. In addition, the structure in the Lerman patent includes inner and outer layers 32 and 34 made from stretchable knitted fabrics that overlie opposite faces of the neoprene base layer 28 (Lerman patent column 4 lines 55-60). On the other hand, the Laghi patent discloses a socket liner that is made of clear, fabric-free silicone having high elongation (Laghi patent column 2 lines 8 and 9). Due to the fact that the basic structures of the two references are totally

different, one having ordinary skill in the art would not have been motivated to incorporate the teachings of one into the other. In addition, there is no teaching or suggestion in the Laghi patent that the silica filler referred to in, for example, column 4 lines 22-36, provides a thermo-regulating affect, as contended by the examiner. Moreover, there is no teaching or suggestion in the references that would have motivated one having ordinary skill in the art to use a silica filler as disclosed by Laghi in the process of making a neoprene rubber sheet of the type used in the structure disclosed in the Lerman patent.

XV.

Claim 26 stands rejected under 35 USC 103(a) as being unpatentable over Lerman (U.S. patent No. 4,832,010) in view of Kristinsson et al. (U.S. patent No. 6,136,039). This rejection is respectfully traversed. The Lerman patent does not disclose a tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for the introduction of said stump and a closed end opposite said open end. Lerman also does not disclose a covering coated on the inside thereof with a polymeric material. Further, Lerman does not disclose a covering coated on all or part of the outside thereof with metallic material. Because Lerman does not disclose a tube sock-shaped covering having a closed end, one having ordinary skill in the art would not have been motivated to modify the device disclosed by Lerman in the manner proposed by the examiner. That is, because the structure disclosed by Lerman is not intended to enclose an amputation stump, one having ordinary skill in the art would not have been motivated to incorporate a docking means as shown at 24 in Kristinsson into the device disclosed by Lerman. Moreover, the docking means disclosed by Kristinsson is not a metallic coating as asserted by the examiner. The docking means 24 disclosed Kristinsson is merely a rigid element that is molded between the inner layer 18 and

the outer layer 20. Moreover, the structure disclosed by Kristinsson comprises a soft inner layer 18 and an a relatively harder outer layer 20 made from silicone (Kristinsson patent column 6 lines 22-33). That structure is totally different from the Lerman structure, which comprises a thin flexible and foldable neoprene rubber layer covered with inner and outer layers of resilient, flexible knitted fabric. Due to the differences between the structures disclosed by Lerman and Kristinsson, one having ordinary skill in the art would not have been motivated to modify Lerman in view of Kristisson as proposed by the examiner. Moreover, even if the proposed modification could be made, it would not result in the claimed structure. Accordingly, the applied references, whether considered alone or in any proper combination, fail to teach or suggest the subject matter in claim 26.

XVI.

In view of the above remarks, applicants submit that claims 16, 17, 23-28, 30, and 31-33 are allowable along with claims 18-20. Therefore, favorable reconsideration and allowance of the present application is respectfully requested.

Respectfully submitted,

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MARKED-UP COPY
Serial No.: 09/418,505
Amendment Filed On: 3/27/02

IN THE SPECIFICATION

On page 1 line 2, please delete the present title and insert therefore:

A TUBE SOCK-SHAPED COVERING

On page 9, delete lines 14-21 (i.e., the paragraph beginning "Figure 1", "Figure 2", and "Figure 3") and insert the following:

Figures 1a and 1b shows a typical pattern for the reflected two-piece form fitting sleeve member according to the invention.

Figure 2A shows a frontal view [(A)] and Figure 2B shows a side view[s] [(B)] of the invention sleeve member enclosing a stump-like form, where 1a and 1b refer to the pattern members of Figures 1a and b, respectively [in Figure 1].

Figures 3a, b, and c show[s] a typical pattern for the optionally banded three-piece form fitting sleeve member according to the invention, the piece [(a)] of Figure 3a being optional [on the Figure 3 pattern]. The piece of Figure 3a [Piece (a)] can also be used in the [Figure 1] pattern of Figures 1a and 1b to provide a top band.

On page 10 delete lines 5-7 (i.e., the paragraph beginning "Figure 7") and insert the following:

Figure 7a show a side view and Figure 7b shows a front view[s] of an invention cushion liner which has a contoured inner surface providing variable thickness cushioning

material at portions of the liner intended to provided particular selective cushioning to the user.

On pages 12 and 13, delete the paragraph beginning on page 12 line 15 and ending on page 13 line 10 and insert the following:

U.S. Applications 08/406,145 and 08/611,305 are incorporated herein by reference. The present invention polymeric gel composition comprises, preferably, a block copolymer and, optionally, mineral oil. The gels of the invention are nonfoamed or foamed with, e.g., a foaming agent. The mineral oil may be present in from 0-95% by weight based on total gel weight, more preferably 70-90% by weight, but also including all of any positive amount including 5, 10, 15, 20, 25, 30, 35, 40, 45, 55, 60, 65, 70, 75, 80, 85, and 90% by weight and all values and ranges in between all these listed values. The invention gel preferably has a durometer (Shore A) of 0 - 20 and preferably a durometer that matches or approximates ($\pm$10%) human skin. Preferably, the oil is present on an equal weight basis, or in a weight ratio of 1/4, with regard to the amount of polymeric material present. More preferably, the gel durometer is from 1-100 Shore 00, most preferably 5-35. The polymeric material present is preferably a styrene isoprene/butadiene block copolymer or styrene-ethylene/butadiene-styrene block copolymer. Preferable examples of such polymeric materials useful herein include C-Flex 1970-W5 (R70-339-000), C-Flex 1960-W5 (both manufactured by Consolidated Polymer Technologies, Largo, Florida, U.S.A.), Kraton G1654 (manufactured by Shell Chemical Co.), Septon 4033, 4044, 4055, 4077, and 4099 (manufactured by Kuraray), DYNAFLEX G6703, G6708, G6713 and G2706 (manufactured by GLS Corp.). For the C-Flex materials a particularly preferred ratio is 1 part oil per 2 parts C-Flex material.

On pages 17 and 18, delete the paragraph being on line 1 of page 17 and ending on line 2 of page 18 and insert the following:

As mentioned above, the invention cushion locking liner comprises docking means for attaching an external device, etc. to the liner. Such docking means includes pins, cables, straps, Velcro® (hook and loop type fasteners), snaps, buckles, buttons, etc. and are typically those which help to attach and support a prosthetic device. Some of these docking means are known in the art and are preferably incorporated in the cushion locking liner by means of direct molding, meaning the molding of an adapter into the fabric possibility by injection, compression, etc. molding, etc. using, preferably, urethane such as an 80 Shore A urethane (Smooth-On PMC-780) after the gel is molded to the fabric. See Figure 12. Such docking means, including distal inserts, can be centered or can be offset to accommodate individual residual limb geometries. Other docking means include molding a raised configuration in the side of the liner which then mates with a recess on the inside of the prosthetic socket, allowing for a locking effect when the user dons the liner and steps into a socket, as well as attaching one or more cables, etc., to the liner which are then drawn through the bottom of the socket. The above mentioned raised configuration might be in the form of one or more bosses (e.g., one on the medial side of socket and/or one on the lateral side of socket) or in the form of an annular ring (see Figures 23 and 24). Such docking means 2 (Figure 12) can also be used to provide additional suspension for a liner by connecting the proximal end of the liner or other cushioning device to a strap, belt, sleeve, etc. which attaches to the body of the wearer. One particular embodiment would be to incorporate the hook or the loop portion of Velcro® directly into the fabric sleeve by sewing or some other means and incorporating a mating piece of hook or loop material into a strap which connects to a waist belt. Such

docking means 3 (Figure 12) can also be used to attach pads to parts of the liner or other cushioning device to fill undesirable voids, or to improve comfort, performance, or appearance. For example, a pad could be attached with snaps to a liner in an area where the amputation stump has shrunk. alternatively, the pad could be attached to the side wall of the socket.

On page 26, delete the paragraph being on line 5 and ending on line 9 and insert the following:

The durability and performance of the sleeve can also be enhanced by fixing the sleeve to the prosthetic socket so that the inner cuff covers the top edge of the prosthetic socket and does not move relative to the top edge of the prosthetic socket. This can be done with adhesive, Velcro® (hook and loop type fasteners), rivets, snaps, buttons, screws, or other methods. The preferred place to make the attachment is at the cuff.

On page 27, please delete the paragraph beginning on line 11 and ending at the bottom of the page and insert the following:

Edge treatment providing some type of finish, as illustrated in Figures 16-19, help to reduce permanent deformation of the sleeve and also help to reduce movement of the sleeve with respect to the wearer's leg. A band of some type of elastic fabric can be sewn to the sleeve edges as illustrated in Figure 16. In Figure 16, the elastic band is illustrated as being attached to an edge of the sleeve by zigzag stitching. In Figure 17, a U-shaped elastic band is illustrated as being positioned over an edge of a sleeve and attached thereto with zigzag stitching. Figure 18 illustrates a sleeve edge finished with an overlock stitch. Figure 19 illustrates a sleeve edge provided with loops adapted to retain a strap made of elastic fabric.

An elastic strap of this type can include overlapping ends that are easily adjusted by use of any conventional fastening devices such as Velcro® (hook and loop type fasteners), snap fasteners, buckles, buttons, etc. On the other hand, the amputee need not use the strap at all if he or she feels it is unnecessary. Other forms of edged treatment could be used including any combination of the above listed types.

On page 36, please delete the paragraph beginning on line 14 and ending on line 21 and insert the following:

A preferred embodiment of the invention is a flat sheet of fabric coated, and/or impregnated with thermoplastic, preferably invention gel, and having a strip of fabric on top of the gel. When the fabric (preferably looped nylon) is rectangular and a rectangular strip of fabric is used on top of cushioning material, the resulting flat sheet can be wrapped around the knee or elbow such that the large fabric piece is on the outside, the small piece of fabric is on the inside and against the knee or elbow, and the gel (thermoplastic) cushioning material contacts the leg or arm above the knee or elbow. The sheet can be held in place with, e.g., [velcro®] Velcro® (hook and loop type fasteners).

On page 38, please delete the paragraph beginning on line 18 and ending on line 21 and insert the following:

A [polatec] Polartec® 2000 stretch laminate fabric having an 85% nylon/15% Lycra® spandex face and a 94% polyester/6% Lycra® spandex back was used to prepare an invention sleeve member using the pattern described in Figure 1. The resultant sleeve member is a form-fitting tubular member for enclosing an amputation stump.

On pages 40 and 41, please delete the paragraph beginning on line 19 on page 40 and ending on line 2 of page 41 and insert the following:

A rectangular shaped piece of looped nylon is placed in the cavity of a rectangular mold. Molten gel is poured over the looped nylon and a rectangular strip of fabric is placed across the middle third of the rectangular mold. The resulting flat sheet can be wrapped around a knee so that the large piece of fabric is on the outside, the small piece of fabric is against the knee, and gel contacts the leg above and below the knee. The flat sheet can be held in place on the leg with the hook portion of Velcro® (hook and loop type fasteners).

IN THE CLAIMS

Claims 16, 17, 23-28, and 30 are reproduced below:

16. (Amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering comprising elastic fabric, said covering including a front portion, a back portion, and a bottom portion, one or both of said front portion and said bottom portion comprising a higher wear resistant elastic fabric and said remaining portion(s) comprising a lower wear resistant highly elastic fabric, said covering being coated on the inside thereof with a foamed or non-foamed polymeric material.

17. (Not amended) A tube sock-shaped covering according to claim 16, wherein said front portion extends from said closed end to said open end and comprises 10% to 90% of said covering.

23. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering comprising fiber-on-end fabric, said covering being

coated on the inside thereof with a polymeric material.

24. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering having a docking means for suspension of the covering to the wearer, and said covering being coated on the inside thereof with polymeric material.

25. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering having a docking means for attaching pads, and said covering being coated on the inside thereof with polymeric material.

26. (Amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end [opposide] opposite said open end, said covering being coated on the inside thereof with polymeric material and coated on all or part of the outside thereof with metallic material.

27. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering being coated on the inside thereof with polymeric material having one or more bosses or annular rings for joining to a prosthetic socket.

28. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end opposite said open end, said covering being coated on the inside thereof with polymeric material, said covering and/or said polymeric material comprising a thermal-regulating additive.

30. (Not amended) A tube sock-shaped covering for enclosing an amputation stump, said covering having an open end for introduction of said stump and a closed end

opposite said open end, said covering comprising fabric that can adhere to a hook portion of a hook and loop fastening system, said covering being coated on the inside thereof with a polymeric material.

31. (New)

32. (New)

33. (New)